

108TH CONGRESS  
1ST SESSION

# H. R. 2932

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2003

Mr. BROWN of Ohio (for himself, Mr. GILCHREST, Ms. SLAUGHTER, Mr. WAXMAN, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Preservation of Antibiotics for Medical Treatment Act of  
6 2003”.

7 (b) TABLE OF CONTENTS.—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title; table of contents.  
 Sec. 2. Findings.  
 Sec. 3. Purpose.

TITLE I—SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS

Sec. 101. Proof of safety of critical antimicrobial animal drugs.

TITLE II—USE OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IN  
 AGRICULTURE

Sec. 201. Collection of data on critical antimicrobial animal drugs produced for  
 agricultural use.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that—

3 (1)(A) in January 2001, a Federal interagency  
 4 task force released an action plan to address the  
 5 continuing decline in effectiveness of antibiotics  
 6 against common bacterial infections, referred to as  
 7 antibiotic resistance;

8 (B) the task force determined that antibiotic re-  
 9 sistance is a growing menace to all people and poses  
 10 a serious threat to public health; and

11 (C) the task force cautioned that if current  
 12 trends continue, treatments for common infections  
 13 will become increasingly limited and expensive, and,  
 14 in some cases, nonexistent;

15 (2) antibiotic resistance, resulting in a reduced  
 16 number of effective antibiotics, may significantly im-  
 17 pair the ability of the United States to respond to  
 18 terrorist attacks involving bacterial infections or a  
 19 large influx of hospitalized patients;

1           (3)(A) any overuse or misuse of antibiotics con-  
2           tributes to the spread of antibiotic resistance, wheth-  
3           er in human medicine or in agriculture; and

4           (B) recognizing the public health threat caused  
5           by antibiotic resistance, Congress took several steps  
6           to curb antibiotic overuse in human medicine  
7           through amendments to the Public Health Service  
8           Act (42 U.S.C. 201 et seq.) made by section 102 of  
9           the Public Health Threats and Emergencies Act  
10          (Public Law 106–505, title I; 114 Stat. 2315), but  
11          has not yet addressed antibiotic overuse in agri-  
12          culture;

13          (4) in a March 2003 report, the National Acad-  
14          emy of Sciences stated that—

15                (A) a decrease in antimicrobial use in  
16                human medicine alone will have little effect on  
17                the current situation; and

18                (B) substantial efforts must be made to  
19                decrease inappropriate overuse in animals and  
20                agriculture;

21          (5)(A) an estimated 70 percent of the anti-  
22          biotics and other antimicrobial drugs used in the  
23          United States are fed to farm animals for nonthera-  
24          peutic purposes, including—

25                (i) growth promotion; and

1           (ii) compensation for crowded, unsanitary,  
2           and stressful farming and transportation condi-  
3           tions; and

4           (B) unlike human use of antibiotics, these non-  
5           therapeutic uses in animals typically do not require  
6           a prescription;

7           (6)(A) many scientific studies confirm that the  
8           nontherapeutic use of antibiotics in agricultural ani-  
9           mals contributes to the development of antibiotic-re-  
10          sistant bacterial infections in people;

11          (B) the periodical entitled “Clinical Infectious  
12          Diseases” published a report in June 2002, based on  
13          a 2-year review by experts in human and veterinary  
14          medicine, public health, microbiology, biostatistics,  
15          and risk analysis, of more than 500 scientific studies  
16          on the human health impacts of antimicrobial use in  
17          agriculture; and

18          (C) the report recommended that antimicrobial  
19          agents should no longer be used in agriculture in the  
20          absence of disease, but should be limited to therapy  
21          for diseased individual animals and prophylaxis  
22          when disease is documented in a herd or flock;

23          (7) the United States Geological Survey re-  
24          ported in March 2002 that—

1 (A) antibiotics were present in 48 percent  
2 of the streams tested nationwide; and

3 (B) almost half of the tested streams were  
4 downstream from agricultural operations;

5 (8) an April 1999 study by the General Ac-  
6 counting Office concluded that resistant strains of 3  
7 microorganisms that cause food-borne illness or dis-  
8 ease in humans—Salmonella, Campylobacter, and E.  
9 coli—are linked to the use of antibiotics in animals;

10 (9)(A) in January 2003, Consumer Reports  
11 published test results on poultry products bought in  
12 grocery stores nationwide showing disturbingly high  
13 levels of Campylobacter and Salmonella bacteria that  
14 were resistant to antibiotics used to treat food-borne  
15 illnesses; and

16 (B) further studies showed similar results in  
17 other meat products;

18 (10) in October 2001, the New England Jour-  
19 nal of Medicine published an editorial urging a ban  
20 on nontherapeutic use of medically important anti-  
21 biotics in animals;

22 (11)(A) in 1999, the European Union banned  
23 the practice of feeding medically important anti-  
24 biotics to animals other than for disease treatment  
25 or control, and prior to that, individual European

1 countries had banned the use of specific antibiotics  
2 in animal feed; and

3 (B) those countries have experienced no signifi-  
4 cant impact on animal health or productivity, food  
5 safety, or meat prices, and more importantly, levels  
6 of resistant bacteria have declined sharply;

7 (12) in 1998, the National Academy of Sciences  
8 noted that antibiotic-resistant bacteria generate a  
9 minimum of \$4,000,000,000 to \$5,000,000,000 in  
10 costs to United States society and individuals yearly;

11 (13) a year later, the National Academy of  
12 Sciences estimated that eliminating the use of all  
13 antibiotics as feed additives would cost each Amer-  
14 ican consumer less than \$5 to \$10 per year;

15 (14) the American Medical Association, the  
16 American Public Health Association, the National  
17 Association of County and City Health Officials, and  
18 the National Campaign for Sustainable Agriculture,  
19 are among the more than 300 organizations rep-  
20 resenting health, consumer, agricultural, environ-  
21 mental, humane, and other interests that support  
22 enactment of legislation to phase out nontherapeutic  
23 use in farm animals of medically important anti-  
24 biotics;

1 (15) the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 301 et seq.)—

3 (A) requires that all drugs be shown to be  
4 safe before the drugs are approved; and

5 (B) places the burden on manufacturers to  
6 account for health consequences and prove safe-  
7 ty;

8 (16)(A) the Food and Drug Administration re-  
9 cently modified the drug approval process for anti-  
10 biotics to recognize the development of resistant bac-  
11 teria as an important aspect of safety;

12 (B) however, most antibiotics currently used in  
13 animal production systems for nontherapeutic pur-  
14 poses were approved before the Food and Drug Ad-  
15 ministration began giving in-depth consideration to  
16 resistance during the drug-approval process; and

17 (C) the Food and Drug Administration has not  
18 established a schedule for reviewing those existing  
19 approvals; and

20 (17) certain non-routine uses of antibiotics in  
21 animal agriculture are legitimate to prevent animal  
22 disease.

23 **SEC. 3. PURPOSE.**

24 The purpose of this Act is to preserve the effective-  
25 ness of medically important antibiotics used in the treat-

1 ment of human and animal diseases by phasing out use  
 2 of certain antibiotics for nontherapeutic purposes in food-  
 3 producing animals.

## 4 **TITLE I—SAFETY OF CRITICAL** 5 **ANTIMICROBIAL ANIMAL DRUGS**

### 6 **SEC. 101. PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL** 7 **ANIMAL DRUGS.**

8 (a) DEFINITIONS.—Section 201 of the Federal Food,  
 9 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by  
 10 adding at the end the following:

11 “(nn) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—  
 12 The term ‘critical antimicrobial animal drug’ means a  
 13 drug that—

14 “(1) is intended for use in food-producing ani-  
 15 mals; and

16 “(2) is composed wholly or partly of—

17 “(A) any kind of penicillin, tetracycline,  
 18 bacitracin, macrolide, lincomycin,  
 19 streptogramin, aminoglycoside, or sulfonamide;  
 20 or

21 “(B) any other drug or derivative of a  
 22 drug that is used in humans or intended for use  
 23 in humans to treat or prevent disease or infec-  
 24 tion caused by microorganisms.

1       “(oo) NONTHERAPEUTIC USE.—The term ‘nonthera-  
 2   peutic use’, with respect to a critical antimicrobial animal  
 3   drug, means any use of the drug as a feed or water addi-  
 4   tive for an animal in the absence of any clinical sign of  
 5   disease in the animal for growth promotion, feed effi-  
 6   ciency, weight gain, routine disease prevention, or other  
 7   routine purpose.”.

8       (b) APPLICATIONS PENDING OR SUBMITTED AFTER  
 9   ENACTMENT.—Section 512(d)(1) of the Federal Food,  
 10   Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amend-  
 11   ed—

12               (1) in the first sentence—

13                       (A) in subparagraph (H), by striking “or”  
 14                       at the end;

15                       (B) by redesignating subparagraph (I) as  
 16                       subparagraph (J); and

17                       (C) by inserting after subparagraph (H)  
 18                       the following:

19                       “(I) with respect to a critical antimicrobial  
 20                       animal drug or a drug of the same chemical  
 21                       class as a critical antimicrobial animal drug,  
 22                       the applicant has failed to demonstrate that  
 23                       there is a reasonable certainty of no harm to  
 24                       human health due to the development of anti-  
 25                       microbial resistance that is attributable, in

1 whole or in part, to the nontherapeutic use of  
 2 the drug; or”; and

3 (2) in the second sentence, by striking “(A)  
 4 through (I)” and inserting “(A) through (J)”.

5 (c) PHASED ELIMINATION OF NONTHERAPEUTIC  
 6 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL  
 7 DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512  
 8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 9 360b) is amended by adding at the end the following:

10 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC  
 11 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL  
 12 DRUGS IMPORTANT FOR HUMAN HEALTH.—

13 “(1) APPLICABILITY.—This subsection applies  
 14 to the nontherapeutic use in a food-producing ani-  
 15 mal of a drug—

16 “(A)(i) that is a critical antimicrobial ani-  
 17 mal drug; or

18 “(ii) that is of the same chemical class as  
 19 a critical antimicrobial animal drug; and

20 “(B)(i) for which there is in effect an ap-  
 21 proval of an application or an exemption under  
 22 subsection (b), (i), or (j) of section 505; or

23 “(ii) that is otherwise marketed for use.

24 “(2) WITHDRAWAL.—The Secretary shall with-  
 25 draw the approval of a nontherapeutic use in food-

1 producing animals described in paragraph (1) on the  
2 date that is 2 years after the date of enactment of  
3 this subsection unless—

4 “(A) before the date that is 2 years after  
5 the date of the enactment of this subsection,  
6 the Secretary makes a final written determina-  
7 tion that the holder of the approved application  
8 has demonstrated that there is a reasonable  
9 certainty of no harm to human health due to  
10 the development of antimicrobial resistance that  
11 is attributable in whole or in part to the non-  
12 therapeutic use of the drug; or

13 “(B) before the date specified in subpara-  
14 graph (A), the Secretary makes a final written  
15 determination under this subsection, with re-  
16 spect to a risk analysis of the drug conducted  
17 by the Secretary and other relevant informa-  
18 tion, that there is a reasonable certainty of no  
19 harm to human health due to the development  
20 of antimicrobial resistance that is attributable  
21 in whole or in part to the nontherapeutic use of  
22 the drug.

23 “(3) EXEMPTIONS.—Except as provided in  
24 paragraph (5), if the Secretary grants an exemption  
25 under section 505(i) for a drug that is a critical

1 antimicrobial animal drug, the Secretary shall re-  
2 scind each approval of a nontherapeutic use in a  
3 food-producing animal of the critical antimicrobial  
4 animal drug, or of a drug in the same chemical class  
5 as the critical antimicrobial animal drug, as of the  
6 date that is 2 years after the date on which the Sec-  
7 retary grants the exemption.

8 “(4) APPROVALS.—Except as provided in para-  
9 graph (5), if an application for a drug that is a crit-  
10 ical antimicrobial animal drug is submitted to the  
11 Secretary under section 505(b), the Secretary shall  
12 rescind each approval of a nontherapeutic use in a  
13 food-producing animal of the critical antimicrobial  
14 animal drug, or of a drug in the same chemical class  
15 as the critical antimicrobial animal drug, as of the  
16 date that is 2 years after the date on which the ap-  
17 plication is submitted to the Secretary.

18 “(5) EXCEPTION.—Paragraph (3) or (4), as the  
19 case may be, shall not apply if—

20 “(A) before the date on which approval  
21 would be rescinded under that paragraph, the  
22 Secretary makes a final written determination  
23 that the holder of the application for the ap-  
24 proved nontherapeutic use has demonstrated  
25 that there is a reasonable certainty of no harm

to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use in the food-producing animal of the critical antimicrobial animal drug; or

“(B) before the date specified in subparagraph (A), the Secretary makes a final written determination under this subsection, with respect to a risk analysis of the critical antimicrobial animal drug conducted by the Secretary and any other relevant information, that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug.”.

## **TITLE II—USE OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IN AGRICULTURE**

### **SEC. 201. COLLECTION OF DATA ON CRITICAL ANTI- MICROBIAL ANIMAL DRUGS.**

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 512 (21 U.S.C. 360b) the following:

1 **“SEC. 512A. COLLECTION OF DATA ON CRITICAL ANTI-**  
2 **MICROBIAL ANIMAL DRUGS.**

3 “(a) IN GENERAL.—Not later than July 1 of each  
4 year, a manufacturer of a critical antimicrobial animal  
5 drug or an animal feed for food-producing animals bearing  
6 or containing a critical antimicrobial animal drug shall  
7 submit to the Secretary a report, in such form as the Sec-  
8 retary shall require, containing information on the sales  
9 during the previous calendar year of the critical anti-  
10 microbial animal drug or the animal feed.

11 “(b) INFORMATION TO BE INCLUDED.—A report  
12 under subsection (a) shall—

13 “(1) state separately the quantity of the critical  
14 antimicrobial animal drug, including such quantity  
15 in animal feed bearing or containing the critical  
16 antimicrobial drug, sold for each kind of food-pro-  
17 ducing animal;

18 “(2) describe the claimed purpose of use for the  
19 drug for each kind of food-producing animal as  
20 being for growth promotion, weight gain, feed effi-  
21 ciency, disease prevention, disease control, disease  
22 treatment, or another purpose; and

23 “(3) describe the dosage form of the drug.

24 “(c) PUBLICATION.—

1           “(1) IN GENERAL.—The Secretary shall make  
2           the information submitted under subsection (a)  
3           available to the public not less than annually.

4           “(2) PROTECTION OF CONFIDENTIALITY.—The  
5           Secretary may aggregate information, if necessary,  
6           so as to avoid disclosure under paragraph (1) of con-  
7           fidential business information.”.

8           (b) VIOLATION.—Subsection (e) of section 301 of the  
9           Federal Food, Drug and Cosmetic Act (21 U.S.C. 331(e))  
10          is amended by striking “515(f)” and inserting “512A,  
11          515(f)”.

12          (c) EFFECTIVE DATE.—The amendments made by  
13          this section shall take effect on January 1, 2005.

○